Modernizing the Regulatory System for Biotechnology Products

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Outline

- Federal policies stretch back to 1986.
- Review principles articulated in policies from the 1980's and 1990's
- Current effort to modernize the regulatory system for products of biotechnology
  - Clarify roles and responsibilities of the agencies that regulate the products of biotechnology
  - Develop a long term strategy
  - Commission an external analysis of future landscape of biotechnology products
- Opportunities for public engagement
- Links to additional information

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History

- In 1986, the White House Office of Science and Technology Policy issued the Coordinated Framework for the Regulation of Biotechnology.

  Developed by an interagency group after input from the public.

  Sought to achieve a balance between regulation adequate to ensure health and environmental safety while maintaining sufficient regulatory flexibility to avoid impeding the growth of an infant industry.

- In 1992, the Coordinated Framework was updated.
- In 2015, the Executive Office of the President announced the start of an interagency process to modernize the biotechnology regulatory system.

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Principles articulated in 1986 policy

- Each agency will use their existing authorities and programs to ensure the safety of the products of biotechnology.
- Should cover the full range of plants, animals, and microorganisms derived by the new genetic engineering techniques.
- To the extent possible, responsibility for a product use will lie with a single agency.
- Where regulatory oversight or review for a particular product is to be performed by more than one agency, coordinated review should occur.
- Because this comprehensive regulatory framework uses a mosaic of existing federal law, some of the statutory nomenclature for certain actions may seem inconsistent.
- The reviews conducted by each of the regulatory agencies are intended to be of comparable rigor.

Principles articulated in 1986 policy

- Following a traditional risk-based approach to regulation, sought to distinguish between those organisms that require a certain level of federal review and those that do not.

- The regulatory framework anticipates that future scientific developments will lead to further refinements. Experience with earlier basic scientific research has shown that as the science progressed and became better understood by the public, regulatory regimens could be modified to reflect more complete understanding of the potential risks involved. Similar evolution is anticipated in the regulation of commercial products as scientists and regulators learn to predict more precisely particular product use that require greater or lesser controls or even exemption from any federal review."

Principles articulated in 1992 update

- There are applications of biotechnology products in many areas, such as medicine and pharmaceuticals, agriculture, energy, manufacturing, and environmental protection.

- The process of modification is thus independent of the safety of the organism. Although the new biotechnology processes can be used to produce risky organisms, so can traditional techniques; it is the characteristics of the organism, the environment, and the application that determine risk (or lack thereof) of the introduction, not the technique used to produce the organism."

  Example criteria or risk factors included the organism's ecological niche, potential for gene exchange, ability to monitor and to mitigate persistence and spread, and potential consequences of dissemination into the greater environment.

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2015 Memo on Modernizing the Regulatory System for Biotechnology Products

- Goals and guidance
  - Federal agencies that regulate biotechnology products should continually strive to improve predictability, increase efficiency, and reduce uncertainty in their regulatory processes and requirements. It is critical that these improvements:
    - maintain high standards that are based on the best available science and that deliver appropriate health and environmental protection;
    - establish transparent, coordinated, predictable, and efficient regulatory practices across agencies with overlapping jurisdiction; and
    - promote public confidence in the oversight of the products of biotechnology through clear and transparent public engagement.

Implementation of the memo

- Established a Biotechnology Working Group under the Emerging Technologies Interagency Policy Coordination Committee

  Includes representatives from:
  - Executive Office of the President
  - EPA
  - FDA
  - USDA

- Three tasks
  1. Update the Coordinated Framework to clarify the current roles and responsibilities of the agencies that regulate the products of biotechnology.
  2. Develop a long-term strategy to ensure that the Federal regulatory system is well-prepared for the future products of biotechnology.
  3. Commission an external, independent analysis of the future landscape of biotechnology products.

(1) Update the Coordinated Framework

- Clarify which biotechnology product areas are within the authority and responsibility of each agency;

- Clarify the roles that each agency plays for different product areas, particularly for those product areas that fall within the responsibility of multiple agencies, and how those roles relate to each other in the course of a regulatory assessment;

- Clarify a standard mechanism for communication and, as appropriate, coordination among agencies, while they perform their respective regulatory functions, and for identifying agency designees responsible for this coordination function; and

- Clarify the mechanism and timeline for regularly reviewing, and updating as appropriate, the Coordinated Framework to minimize delays, support innovation, protect health and the environment and promote the public trust in the regulatory systems for biotechnology products.

(2) Long-term strategy

- Transparency

  establish a timetable and mechanisms to work with stakeholders to identify impediments to innovation, focusing on building new, and augmenting existing, stakeholder collaborations to inform efforts, increase transparency, streamline processes, reduce costs and response times, and ensure the protection of health and the environment;

  coordinate the development of tools and mechanisms for assisting small businesses developing biotechnology products to navigate the regulatory system;

  initiate development of a modernized, user-friendly set of tools for presenting the regulatory agencies authorities, practices, and bases for decision making for the regulation of biotechnology products to the public, including digital services to improve the interactions between the FDA, EPA, USDA, the general public, and product developers and updating these tools and practices regularly to ensure optimal transparency; and

  proactively engage with the public to discuss how the Federal government uses a risk-based, scientifically sound approach to regulating the products of biotechnology, and clearly communicating to the public which types of products are regulated, which types of products are not regulated, and why.

(2) Long-term strategy

- Support the science that underpins the regulatory system
  - work with other Federal agencies, as appropriate, to develop a coordinated and goal-oriented plan for supporting the science that informs regulatory activities;

- Predictability and Efficiency

  develop a plan for periodic formal horizon scanning assessments of new biotechnology products;

  - identify changes to authorities, regulations, and policies, if any, that could improve agencies' abilities to assess expeditiously the potential impacts and risks arising from future products of biotechnology and to ensure the transparency, predictability, and efficiency of regulatory oversight for such products; and
  - ensure that product evaluations are risk-based and grounded in the best science available, including regularly adjusting regulatory activities based on experience with specific products and the environments into which those products have been introduced.

(3) External, independent analysis of future landscape

- External, independent analysis of the future landscape of biotechnology products that will identify

  (1) potential new risks and frameworks for risk assessment and

  (2) areas in which the risks or lack of risks relating to the products of biotechnology are well understood.

- The review will help inform future policy making.

- The National Academies of Sciences, Engineering, and Medicine have already been asked to conduct such an analysis.

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Next steps

- Request for Information currently open (Responses must be received by November 13, 2015 at 5:00 PM EST):

  Interagency Request for Information (RFI) to solicit relevant data and information, including case studies, that can assist in the development of the proposed update to the Coordinated Framework for the Regulation of Biotechnology (CF) to clarify the current roles and responsibilities of the EPA, FDA, and USDA and the development of a long term strategy consistent with the objectives described in the July 2, 2015 EOP memorandum.

- Two more public meetings

- The update to the Coordinated Framework will undergo public comment before it is finalized.

Request for Information questions

- What additional clarification could be provided regarding which biotechnology product areas are within the statutory authority and responsibility of each agency?

- What additional clarification could be provided regarding the roles that each agency plays for different biotechnology product areas, particularly for those product areas that fall within the responsibility of multiple agencies, and how those roles relate to each other in the course of a regulatory assessment?

- How can Federal agencies improve their communication to consumers, industry, and other stakeholders regarding the authorities, practices, and bases for decision-making used to ensure the safety of the products of biotechnology?

- Are there relevant data and information, including case studies, that can inform the update to the CF or the development of the long-term strategy regarding how to improve the transparency, coordination, predictability, and efficiency of the regulatory system for the products of biotechnology?

- Are there specific issues that should be addressed in the update of the CF or in the long-term strategy in order to increase the transparency, coordination, predictability, and efficiency of the regulatory system for the products of biotechnology?

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For additional information

- 1986 Coordinated Framework for Regulation of Biotechnology
  https://www.aphis.usda.gov/brs/fedregister/coordinated framework.pdf
- 1992 Update to Coordinated Framework: Exercise of Federal Oversight Within Scope of Statutory Authority: Planned Introductions of Biotechnology Products Into the Environment
  https://www.whitehouse.gov/sites/default/files/microsites/ostp/57_fed_reg_6753__1992.pdf
- 2015 EOP Memo and Blog post: Modernizing the Regulatory System for Biotechnology Products
  https://www.whitehouse.gov/sites/default/files/microsites/ostp/modernizing_the reg_system_for_biotech products me mo_final.pdf
  https://www.whitehouse.gov/blog/2015/07/02/improving transparency-and-ensuring-continued-safety biotechnology
- Other Relevant Policy Documents

  Improving Regulation and Regulatory Review", Executive Order 13563, January 18, 2011.
  - http://www.gpo.gov/fdsys/pkg/FR-2011-01-21/pdf/2011-1385.pdf

  Principles for Regulation and Oversight of Emerging Technologies", Memorandum for the Heads of Departments and Agencies, March 11, 2011.
  - https://www.whitehouse.gov/sites/default/files/omb/inforeg/for-agencies/Principles-for-Regulation-and-Oversight of-Emerging-Technologies new.pdf

  Identifying and Reducing Regulatory Burdens", Executive Order 13610, January 10, 2012.
  - https://www.whitehouse.gov/sites/default/files/docs/microsites/omb/eo_13610_identifying_and_reducing_regulatory burdens.pdf